

## REMARKS

The undersigned thanks the Examiner for the courtesy of an in-person interview of this case on February 26, 2003. While the Interview Summary has not yet been received, it was the understanding of the undersigned that one would be mailed, and that applicant did not need to summarize the interview.

### *New Matter Rejections*

That having been said, one topic of discussion were the 'new matter' rejections. Applicant provided a copy of the relevant MPEP section 608.01(p) which authorizes the incorporation of the subject matter added in the Rule 116 Amendment of August 29, 2002. A courtesy copy of that section is attached hereto. Applicants have represented (and supplemented) the text and figures to be included.

### *Drawings*

The drawings to be added in the Rule 116 Amendment are taken identically from the parent cases which are expressly incorporated by reference. The earlier issued patents include the (See the "Cross Reference To Related Applications" found at page 1, lines 3 thru 19) Figs. 11 and 12 (as Figs. 4 and 10, respectively).

### *Claim Rejections – Section 112*

The Section 112 first paragraph rejection is addressed by the 'new matter' section, above. The structure of fig. 12 (Fig. 4 in the parent cases) particularly supports the claims. Various features

in the dependent claims is found in the other text and figures. The specification now provides (via the subject matter added at page 1 of the Rule 116 Amendment):

FIG. 12 shows a perspective view of detail of ePTFE sheet material with a partial thickness pattern of simple cuts and/or channels which results in numerous individual villi of ePTFE and great irregularity of the surface of the material. Additional patterns of cuts or troughs may be made along any other axis as indicated, for example, by the arrows.

Applicant has extracted the exact language from specification, such as “channels”, in the claim as presented. Accordingly, the section 112 first paragraph rejections are believed to be overcome.

The section 112 second paragraph rejections will be treated serially.

The term “sheet-like” has been replaced with the affirmative term “sheet”.

Claim 13 no longer contains the cited language.

Claim 96 now recites “periodic” instead of “predictable”.

Claims 106 – 109 have been amended as suggested by the Examiner.

Claim 111 has been deleted.

Claims 113 and 114 are believed to be supported by the specification, e.g., Rule 116 Amendment at page 2, second full paragraph (“The implant coverings usable in connection with this invention may be manufactured from any material which promotes limited tissue ingrowth into the material, and has a high biocompatibility and low reactivity and disorganizes scar tissue at the implant/body interface.”)

Claim 115 has been cancelled.

Claims 116 – 121 are believed to be definite in that claim 116 recites “further including” the device, and that the dependent claims therefore also include that limitation.

Claims 123-126 have been amended to recite the “sheet”.

***Art Based Rejection***

The subject matter of the claims is now all supported in the application having priority of the December 22, 1987 filing. As such, the cited references have been overcome. Further, it is believed that the claims as now presented clearly distinguish over the art of record. Applicant appreciates the Examiner having signed off on the 1449.

***Conclusion***

Prompt and favorable action on the merits of the claims is earnestly solicited. If any minor issues remain, please contact Applicants’ undersigned representative at 949-737-2900.

Respectfully submitted,

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## I. INCORPORATION BY REFERENCE

The Commissioner has considerable discretion in determining what may or may not be incorporated by reference in a patent application. *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968). The incorporation by reference practice with respect to applications which issue as U.S. patents provides the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The following is the manner in which the Commissioner has elected to exercise that discretion. Section A provides the guidance for incorporation by reference in applications which are to issue as U.S. patents. Section B provides guidance for incorporation by reference in benefit applications; i.e., those domestic (35 U.S.C. 120) or foreign (35 U.S.C. 119(a)) applications relied on to establish an earlier effective filing date.

### A. *Review of Applications Which Are To Issue as Patents.*

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, *Ex parte Schwarze*, 151 USPQ 426 (Bd. App. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below.

"Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, essential material may not be incorporated by reference to (1) patents or applications published by foreign countries or a regional patent office, (2) non-patent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.

Nonessential subject matter may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional

patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications however, hyperlinks and/or other forms of browser executable code cannot be incorporated by reference. See MPEP § 608.01. Nonessential subject matter is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art.

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. Guidelines for situations where applicant is permitted to fill in a number for Application No. \_\_\_\_\_ left blank in the application as filed can be found in *In re Fouché*, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending applications; both types are open to the public upon the referencing application issuing as a patent. See MPEP § 103).

### 1. Complete Disclosure Filed

If an application is filed with a complete disclosure, essential material may be canceled by amendment and may be substituted by reference to a U.S. patent or an earlier filed pending U.S. application. The amendment must be accompanied by an affidavit or declaration signed by the applicant, or a practitioner representing the applicant, stating that the material canceled from the application is the same material that has been incorporated by reference.

If an application as filed incorporates essential material by reference to a U.S. patent or a pending and commonly owned U.S. application, applicant may be required prior to examination to furnish the Office with a copy of the referenced material together with an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the copy consists of the same material incorporated by reference in the referencing application.

However, if a copy of a printed U.S. patent is furnished, no affidavit or declaration is required.

Prior to allowance of an application that incorporates essential material by reference to a pending U.S. application, the examiner shall determine if the referenced application has been published or issued as a patent. If the referenced application has been published or issued as a patent, the examiner shall enter the U.S. Patent Application Publication No. or the U.S. Patent No. of the referenced application in the specification of the referencing application (see MPEP § 1302.04). If the referenced application has not been published or issued as a patent, applicant will be required to amend the disclosure of the referencing application to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating the amendatory material consists of the same material incorporated by reference in the referencing application.

## 2. Improper Incorporation

The filing date of any application wherein essential material is improperly incorporated by reference to a foreign application or patent or to a publication will not be affected because of the reference. In such a case, the applicant will be required to amend the specification to include the material incorporated by reference. The following form paragraphs may be used.

### ¶ 6.19 Incorporation by Reference, Foreign Patent or Application

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

#### ¶ 6.19.01 Improper Incorporation by Reference, General

The attempt to incorporate subject matter into this application by reference to [1] is improper because [2].

#### Examiner Note:

1. In bracket 1, identify the document such as an application or patent number or other identification.

2. In bracket 2, give reason why it is improper.

The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Reliance on a commonly assigned copending application by a different inventor may ordinarily be made for the purpose of completing the disclosure. See *In re Fried*, 329 F.2d 323, 141 USPQ 27 (CCPA 1964), and *General Electric Co. v. Brenner*, 407 F.2d 1258, 159 USPQ 335 (D.C. Cir. 1968).

Since a disclosure must be complete as of the filing date, subsequent publications or subsequently filed applications cannot be relied on to establish a constructive reduction to practice or an enabling disclosure as of the filing date. *White Consol. Indus., Inc. v. Vega Servo-Control, Inc.*, 713 F.2d 788, 218 USPQ 961 (Fed. Cir. 1983); *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974); *In re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

### B. Review of Applications Which Are Relied on To Establish an Earlier Effective Filing Date.

The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120. Neither 35 U.S.C. 119(a) nor 35 U.S.C. 120 places any restrictions or limitations as to how the claimed invention must be disclosed in the earlier application to comply with 35 U.S.C. 112, first paragraph. Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. See *Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).

The reason for incorporation by reference practice with respect to applications which are to issue as U.S. patents is to provide the public with a patent disclosure which minimizes the public's burden to search for and obtain copies of documents incorporated by

reference which may not be readily available. Through the Office's incorporation by reference policy, the Office ensures that reasonably complete disclosures are published as U.S. patents. The same policy concern does not apply where the sole purpose for which an applicant relies on an earlier U.S. or foreign application is to establish an earlier filing date. Incorporation by reference in the earlier application of (1) patents or applications published by foreign countries or regional patent offices, (2) nonpatent publications, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application, is not critical in the case of a "benefit" application.

When an applicant, or a patent owner in a reexamination or interference, claims the benefit of the filing date of an earlier application which incorporates material by reference, the applicant or patent owner may be required to supply copies of the material incorporated by reference. For example, an applicant may claim the benefit of the filing date of a foreign application which itself incorporates by reference another earlier filed foreign application. If necessary, due to an intervening reference, applicant should be required to supply a copy of the earlier filed foreign application, along with an English language translation. A review can then be made of the foreign application and all material incorporated by reference to determine whether the foreign application discloses the invention sought to be patented in the manner required by the first paragraph of 35 U.S.C. 112 so that benefit may be accorded. *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

## II. SIMULATED OR PREDICTED TEST RESULTS OR PROPHETIC EXAMPLES

Simulated or predicted test results and prophetic examples (paper examples) are permitted in patent applications. Working examples correspond to work actually performed and may describe tests which have actually been conducted and results that were achieved. Paper examples describe the manner and process of making an embodiment of the invention which has not actually been conducted. Paper examples should not be represented as work actually done. No results should be represented as actual results unless they have actually been achieved. Paper examples should not be described using the past tense.

For problems arising from the designation of materials by trademarks and trade names, see MPEP § 608.01(v).

## 608.01(q) Substitute or Rewritten Specification

### 37 CFR 1.125. *Substitute specification.*

(a) If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof, be rewritten.

(b) A substitute specification, excluding the claims, may be filed at any point up to payment of the issue fee if it is accompanied by:

(1) A statement that the substitute specification includes no new matter; and

(2) A marked up version of the substitute specification showing all the changes (including the matter being added to and the matter being deleted from) to the specification of record. Numbering the paragraphs of the specification of record is not considered a change that must be shown pursuant to this paragraph.

(c) A substitute specification submitted under this section must be submitted in clean form without markings as to amended material. The paragraphs of any substitute specification, other than the claims, should be individually numbered in Arabic numerals so that any amendment to the specification may be made by replacement paragraph in accordance with § 1.121(b)(1).

(d) A substitute specification under this section is not permitted in a reissue application or in a reexamination proceeding.

The specification is sometimes in such faulty English that a new specification is necessary; in such instances, a new specification should be required.

Form paragraph 6.28 may be used where the specification is in faulty English.

### ¶ 6.28 *Idiomatic English*

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter.

37 CFR 1.125(a) applies to a substitute specification required by the Office. If the number or nature of the amendments or the legibility of the application papers renders it difficult to consider the application, or to arrange the papers for printing or copying, the Office may require the entire specification, including the claims, or any part thereof be rewritten.